

REMARKS

Applicants gratefully acknowledge the Examiner's withdrawal of the previous 35 U.S.C. § 102 and § 103 rejections in view of Applicants' amendment filed on 24 September 2003.

Claims 1-6, 8-11 and 13-16 are currently pending in the application of which claims 1, 9 and 14 are independent. By this amendment, claims 1, 5, 6, 8, 9, 11, 13, 14 and 16 have been amended and claims 4, 10 and 15 have been cancelled. Applicants reserve the right to file continuation or divisional applications directed to the subject matter of any claim cancelled for any reason.

The amendment to claims 1, 5, 6, 8, 9, 11, 13, 14 and 16 have been made to more clearly define and distinctly claim the inventions defined herein. The amendment to claim 1, 5, 6, 8, 9, 11, 13, 14 and 16 are fully supported by the specification and original claims. It is submitted that no new matter has been introduced by the present amendment and entry of the same is respectfully requested. By these amendments, Applicants do not disclaim any subject matter to which the Applicants are entitled.

In view of the above amendments and the following Remarks, Applicants respectfully request reconsideration and timely withdrawal of the pending objections and rejections for the reason discussed below.

Rejections Under Non-Statutory Double Patenting

The Examiner has rejected claims 1-4, 6, 8-11, and 13-16 "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 6,475,984," stating "although the conflicting claims are not identical, they are not patentable distinct from each other because they both encompass methods of administering leptin to a premature infant." Office Action at page 3. Applicants respectfully traverse.

The requirements for a rejection under the judicially created doctrine of obviousness-type double patenting are similar to the requirements for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. However, the exception exists that the patent principally underlying an obviousness-type double patenting rejection is not considered prior art. As set forth in M.P.E.P. § 804(II)(B)(1), the factual inquiries that are applied for establishing a *prima facie* case of obviousness under 35 U.S.C. §103 are also employed when making an obviousness-type double patenting rejection. Accordingly, to make an obviousness-type double patenting rejection, three basic criteria must be met.

First, the prior art reference (or references when combined) and a claim of the patent principally underlying the obviousness-type double patenting rejection must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation in the prior art references themselves to modify the claim of the patent principally underlying the obviousness-type double patenting rejection or to combine the prior art reference teachings with the claim of the patent principally underlying the obviousness-type double patenting rejection. Third, there must be a reasonable expectation of success for the modification or combination of prior art references and the claim of the patent principally underlying the obviousness-type double patenting rejection. Further, the teaching or suggestion to make the modification or combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. Additionally, there must be particular finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge to the claimed invention to make a combination or modification of the claim of the patent principally underlying the obviousness-type double patenting rejection.

M.P.E.P. § 2143.

The Examiner fails to meet the requisite criteria to support an obviousness-type double patenting rejection. Specifically, the Examiner has failed to show that claims 2-11 of U.S. Patent No. 6,475,984 ('984) teach or suggest all the claim limitations of the instant application. The pending claims of the instant application are directed to methods for improving lung surfactant production in an individual with impaired surfactant production by administering leptin or a biologically active fragment of leptin thereof. Claims 2-11 of the '984 patent are related to a method for increasing the growth of a small-for-gestational age infant by administering leptin. Nowhere do the claims 2-11 of the '984 patent teach or suggest augmenting surfactant production in individuals with impaired lung surfactant production. Therefore, claims 2-11 of the '984 patent do not support an obviousness-type double patenting rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of claims 1-4, 6, 8-11 and 13-16.

Next, the Examiner has provisionally rejected claims 1-4, 6, 8-11 and 13-16 under "the doctrine of obviousness-type double patenting as being unpatentable over claim 34 of copending Application No. 10/286,947," alleging that the claims are not patentable distinct because "claim 34 of copending Application No. 10/286,947 encompasses providing leptin to a subject requiring leptin therapy to treat a condition by administering milk fat globules containing about 50ng/ml to 100 ng/ml of leptin." Office Action at page 3. Applicants respectfully traverse.

As discussed above, in order to establish an obviousness-type double patenting rejection, the claims of the alleged application must teach or suggest each and every element of the presently claimed invention. Indeed, nowhere does claim 34 of copending Application No. 10/286,947 teach or suggest augmenting surfactant production in individuals with impaired lung surfactant production by administering leptin or a biologically active fragment thereof.

Therefore, the Examiner has failed to meet the requisite criteria to support an obviousness-type double patenting rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of claims 1-4, 6, 8-11 and 13-16.

Finally, the Examiner rejected claim 5 under the “doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 6,475,984 in view of Pellemounter et al...,” alleging “that it would have been *prima facie* obvious to supplement the milk fat globules with the recombinant leptin (obese gene product) of Pellemounter in order to increase the administered dose of leptin.” *Id.* Applicants respectfully traverse. Claim 5 depends from claim 1 and thus includes all of the limitations of claim 1 by virtue of its dependency. Claims 2-11 of the ‘984 patent fail to teach or suggest a method for augmenting surfactant production by administering leptin or a biologically active fragment thereof to an individual with impaired surfactant production. Pellemounter is not adequate as a secondary reference because it fails to teach or suggest augmenting lung surfactant production in an individual with impaired surfactant production by administering leptin or a biologically active fragment of leptin thereof. Rather, Pellemounter is directed to the role of the obese (OB) gene in the regulation of body weight and adiposity in mice. More specifically, Pellemounter suggests that the OB protein regulates body weight and fat deposition through effects on metabolism and appetite. Therefore, claims 2-11 of the ‘984 patent, either singly or in combination with Pellemounter, do not teach or suggest each and every element of the claimed invention and therefore do not support an obviousness-type double patenting rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present obviousness-type double patenting rejection of claim 5.

Rejections Under 35 U.S.C. §112, second paragraph

Claims 1-4, 6, 8-11 and 13-16 were rejected under 35 U.S.C. § 112, second paragraph “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” *Id.* at page 4. Without acquiescing to the propriety of the Examiner’s rejection and in order to expedite prosecution of the pending application, Applicants have amended claims 1, 5, 6, 8, 9, 11, 13, 14 and 16 to delete the phrase “leptin compound” and replace it with a “leptin compound or a biologically active fragment thereof.” Additionally, Applicants have canceled claims 4, 10 and 15.

These amendments are not made for the purpose of avoiding prior art or narrowing the claimed invention, and no change in claim scope is intended. Therefore, Applicants do not intend to relinquish any subject matter by these amendments. Applicants respectfully submit that claims 1, 5, 6, 8, 9, 11, 13, 14 and 16, as amended, fully comply with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection of the claims 1-4, 6, 8-11 and 13-16.

CONCLUSION

Applicants believe that a full and complete response has been made to the pending Office Action and respectfully submit that all grounds for rejection have been overcome or rendered moot. Accordingly, Applicants respectfully submit that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the Applicants' undersigned representative at the number below to expedite prosecution.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,



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